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10.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

The submitter of this premarket notification is:

Egon Pfeil
Regulatory Affairs
Agilent Technologies
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Germany
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This summary was prepared on: April 17, 2000

Device name: Agilent family of Patient Monitors individually known as the M1175A/76A/77A (CMS), the M1205A (24/26), and the M3000A/M3046A (M3/4).

Common name: Patient Monitor

Classification names

Regulation Number	Classification Name
870.1435	Computer, Diagnostic, Pre-Programmed, Single-Function
870.1025	Detector and Alarm, Arrythmia
870.2900	Cable, Transducer and Electrode, Patient (including connector)
870.1110	Computer, Blood-Pressure
870.1120	Cuff, Blood-Pressure
870.1130	System, Measurement, Blood-Pressure, Noninvasive

Predicate Devices: The modified device is substantially equivalent to previously cleared Agilent devices marketed pursuant to K971910, K981576, K990125, K990972, and K903771.

Modification: The modification is a software based change that involves only the adult/pediatric NIBP algorithm of the measurement computer processing unit of each device.

Intended Use: The modified device has the same intended use as the legally marketed predicate devices. When used in the hospital environment, the device is intended for measuring and displaying, recording and alarming multiple physiological parameters and waves in adult, pediatric and neonatal patients.

Technological characteristics	The modified device has the same technological characteristics as the legally marketed predicate devices.
Testing	Verification, validation, and testing activities were conducted to establish the performance and reliability characteristics of the modified NIBP algorithm using neonatal and adult patient data. Testing involved system level tests, integration tests, safety testing from hazard analysis, interference testing, and hardware testing. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence. Clinical performance evaluations using the new algorithm were conducted with ICU, OR, and post-anesthesia neonate and adult patients to validate the noninvasive measurement of blood-pressure against an intra-atrial reference. Similarly, reusable cuffs were clinically evaluated to validate several minor dimensional changes. All tested module and cuff combinations passed test criteria and test results showed substantial equivalence. No adverse events were caused by the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2000

Mr. Egon Pfeil
Regulatory Affairs
Agilent Technologies
Deutschland GmbH
Herrenberger Strasse 130
D-71034 Boeblingen
GERMANY

Re: K001333
Agilent Component Monitoring System, M1175A, M1176A, M1177A /Agilent M1205A, Release C and Agilent M3000A/M3046A Patient Monitor, Release L.
Regulatory Class: III (three)
Product Code: DSI
Dated: April 17, 2000
Received: April 27, 2000

Dear Mr. Pfeil:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.1 ODE Indications Statement

Indications for Use Statement

510(k) Number (if known) K001333

Device Name

The Agilent Technologies family of patient monitors. These devices are individually known as the Agilent Component Monitoring System M1175A, M1176A, M1177A /Agilent M1205A, Rel.C and the Agilent M3000A/M3046A Patient Monitor, Rel. L.

Indications for Use

The Agilent family of patient monitor products is intended for monitoring, recording, and alarming of multiple physiological parameters. The devices are indicated for use in health care facilities by health care professionals whenever there is a need for monitoring the physiological parameters of adult, neonatal, and pediatric patients.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001333

Prescription Use V (Per 21 CFR 801.109) OR Over-The-Counter Use _____